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APPLICATION NO.		FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/501,217	09/501,217 02/10/2000		Howard Murad	2267-017	2267-017 3548	
20582	7590	03/22/2002				
PENNIE &			EXAMINER			
1667 K STR SUITE 1000		V		CHANNAVAJJALA, LAKSHMI SARADA		
WASHINGTON, DC 20006				ART UNIT PAPER NUMBER		
				1615 DATE MAILED: 03/22/2002	10	

Please find below and/or attached an Office communication concerning this application or proceeding.

<del></del>		La di N				
		Application No.	Applicant(s)			
	Office Action Comments	09/501,217	MURAD, HOWARD			
	Office Action Summary	Examiner	Art Unit			
TI WALL WO DATE CHI		Lakshmi S. Channavajjala	1615			
Period fo	<ul> <li>The MAILING DATE of this communication app</li> <li>Reply</li> </ul>	ears on the cover sheet with the c	orresponaence adaress			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status 1)⊠	Responsive to communication(s) filed on <u>01 F</u>	Sahruany 2002				
2a)□		is action is non-final.				
3)	,		recognition as to the morits is			
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims						
4)⊠ Claim(s) <u>1,2,4-9 and 11-27</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1,2,4-9 and 11-27</u> is/are rejected.						
7)	Claim(s) is/are objected to.					
8)[	Claim(s) are subject to restriction and/or	election requirement.				
Application Papers						
9) The specification is objected to by the Examiner.						
10)[] 7	he drawing(s) filed on is/are: a)□ accep	ted or b)□ objected to by the Exa	miner.			
	Applicant may not request that any objection to the					
11)∐ 1	he proposed drawing correction filed on	is: a)□ approved b)□ disappro	oved by the Examiner.			
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
	<ol> <li>Certified copies of the priority documents</li> </ol>	s have been received.				
	2. Certified copies of the priority documents have been received in Application No					
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) ☐ The translation of the foreign language provisional application has been received.  15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
2) Notice	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal I	(PTO-413) Paper No(s) Patent Application (PTO-152)			
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#### **DETAILED ACTION**

Receipt of request under 37 CFR 1.114 for RCE and preliminary amendment C, dated 2-1-02 is acknowledged.

## Claim Rejections - 35 USC § 112

Claims 7, 11, 13, 15, 16, 18, 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 requires a moisturizing agent selected form "primrose oil, flax seed oil etc.", however, the claim does not specify if the required moisturizing agent is a further limitation of the hydrophobic or hydrophilic moisturizing agent of claim 1. According to the specification, the moisturizing agents of claim 7 do not belong to either hydrophobic or hydrophilic group of moisturizing agents.

Claim 11, a dependent claim of 11 further recites the amounts of the components of claim 1. Claim 11 which recites various amounts of different components, recites "if present" which is indefinite because, the expression does not clearly require the component present.

Also Claim 11 recites the limitation "magnesium, copper and manganese". There is insufficient antecedent basis for this limitation in the claim.

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Similarly, claims 13, 15 & 18 recite the expression "if present" which is vague as it is not clear if any extract is present or not. If applicants choose to include one of the components of claims 11, 13, 15 and 18, it is suggested that the word "if present" is deleted.

Claim 16 recites "vitamin E source", which is indefinite because it is not clear if the source or the vitamin E itself possess the anti-inflammatory activity. Examiner notes that on page 19 of the specification, applicants describe only a sulfate or succinate Vitamin E complex as an optional ingredient that assist in inhibiting or reducing inflammation, but not anti-inflammatory by itself.

Claim 21 recites "vitamin A source", "vitamin C source" etc., which is indefinite because it is not clear if the vitamins themselves act as antioxidants or do their sources.

A clarification and appropriate correction is requested.

#### Claim Objections

Claim 5 is objected to because of the following informalities: the word "seramides", should read "ceramides". Appropriate correction is required.

#### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 09/501,218. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims directed to a method of managing one or more dermatological conditions utilizes the same a composition that reads on the instant claimed composition. Accordingly, the instant composition is over the copending claims.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

## Claim Rejections - 35 USC § 102

Claims 24-27 are rejected under 35 U.S.C. 102(a) as being anticipated by USPN 5,985,300 to Crotty et al (Crotty).

Crotty discloses skin care compositions containing fruit extracts, zinc salts and other components such as ceramides, vitamins, mono- or polyhydroxy acids etc. See abstract, col. 4, lines 15-22 and col. 5, lines 12-40. In particular, Crotty teaches N-acetyl cysteine, which meets the requirement of instant cysteine component (col. 4, lines 10-14). Crotty teaches fruit extracts

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such as grape fruit, strawberry, vanilla fruit, blackberry fruit etc., as anti-oxidants and free-radical inhibitors (col. 3). Accordingly, absent evidence on the contrary, the fruit extracts of Crotty have the capability to neutralize free radicals. Further, Crotty teaches herbal extracts for sebum/oil control include wheat (col. 4, lines 15-20), which reads on hydrophilic moisturizing agent and ceramides (abstract) as well as tocopherol linoleate (col. 4, lines 2-3) Accordingly, Crotty anticipates the instant claims 24-27.

# Claim Rejections - 35 USC § 103

Claims 1, 2, 4-9 and 11-27 are rejected under 35 U.S.C. 103(a) as being unpatentable 5,985,300 to Crotty et al in view of US 5,571,503 to Mausner and 5,891,440 to Lansky.

Crotty discloses skin treatment compositions (i.e., dermatological agent) containing fruit extracts, plant extracts such as rosemary, soy, Echinacea, ginko etc., phytoestrogens, herbal extracts, alpha- and beta-hydroxycarbolic acids, anti-inflammatory, vitamins, flavonoids etc., all of which read on the claimed moisturizers, sunscreens, transition metals, anti-inflammatory agents, immunity boosting agents, ceramides, zinc salts etc. See col. 2, lines 40 through col. 5, lines 43, for individual vitamins, hydroxycarboxylic acids, plant or herbal extracts and other components. Crotty suggests adding phytroestrogens in their skin care compositions because of their antioxidant or free radical inhibiting activity. See table in col. 3. However, Crotty fails to teach pomegranate extract in their composition and also fails to specifically mention a combination of hydrophilic and hydrophobic moisturizing agents.

Mausner discloses anti-pollution cosmetic composition, which incorporates a combination of ingredients for skin protection from environmental pollution, while providing

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significant protection against moisture loss and damage due to free radical activity and UV light (col. 7, lines 7-30). The composition comprises an anti-pollution complex comprising wheat protein, mannitol, glycerol etc., micellar complex comprising phospholipids & hyaluronate, and anti-free radical complex comprising tocopherol, ascorbic acid etc., (col. 1, lines 35-68 & col. 8). This complex provides hydration to skin, as well as healing, soothing, calming and non-irritant activities (col. 9, lines 14-45), Further, Mausner teaches addition of ancillary (preferable) ingredients such as a hydrophilic component and a lipid-soluble component, which include the claimed dimethicone, glycerin etc. (col. 2, lines 38-65, col. 3, lines 5-10 & col. 11-12). Further, Mausner teaches addition of sunscreen (col. 9) in the composition, including the sunscreens of instant claim 9. The anti-free radical complex includes Vitamin A, vitamin E and vitamin C (col. 9-10) Mausner also teaches several herbal extracts such as aloe, matricaria etc 9col. 10). Although Mausner does not specifically teach a combination of moisturizing agents as in the instant claim, glycosphingolipids read on the instant hydrophobic moisturizing component; hydrolyzed wheat protein & hyaluronate read on hydrophilic component. Mausner also discloses a fruit extract such as apricot kernel in their composition. In particular, the composition in col. 3-4, recites a composition containing specified amounts of various components including dimethicone (a hydrophobic agent of instant claim 5), sodium pyrrolidone carboxylic acid and sodium hyaluronte (the hydrophilic agents of instant claim 4), fruit extract such as apricot kernel, tocopherol and ascorbyl palmitate. Mausner does not teach pomegranate extracts.

Lansky described above, teaches pomegranate extracts in topical composition for supplementing phytoestrogens. Lansky teaches extracting pomegranate seeds and admixing with other herbal extracts such as licorice (col. 4) and using as a skin cream (abstract, col. 2, lines 3-

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36) Further, Lansky recognizes that pomegranate seed extracts have been used for treating oily skin (col. 2, lines 20-23). Lansky teaches topical as well as oral administration of phytoestrogens.

Accordingly, it would have been obvious for one of an ordinary skill in the art to add phytoestrogen containing pomegranate extracts of Lansky, as a phytoestrogen, to the skin care composition of Crotty because Lansky teaches the phytoestrogens of pomegranate provide skin care and can be used for oily skin and Crotty recognizes that the phytoestrogens also provide anti-oxidant effects in protecting the skin. Thus, a skilled artisan would expect to provide both skin care in general and anti-oxidant effect with pomegranate extract of Lansky in the composition of Crotty. Further, it would have been obvious for a skilled artisan at the time of the instant invention to add the micellar components, lipophilic and hydrophilic components, as well as sunscreens of Mausner in the cosmetic composition of Crotty because Mausner teaches that micellar components, lipophilic and hydrophilic provide excellent hydration to the skin and the sunscreens provide skin protection from UV-A and UV-B radiation of sunlight.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala (lakshmi.channavajjala@uspto.gov) whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM - 4.00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7921/7924 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Lakshmi Channavajjala March 18, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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